

**Summary of Veterinary Product Characteristics**  
**GENTALUX**

**1. GENERAL PRODUCT INFORMATION**

1.1 Gentalux.

1.2 Gentalux is an antibacterial veterinary medicinal product in the form of a solution for injection, is clear, almost colourless or light yellow liquid, 1 ml contains 40 mg of gentamicin (in the form of sulphate) as an active substance and excipients - sodium sulphite, Trilon B , water for injections.

1.3 The veterinary medicinal product is packed in glass vials of appropriate capacity - 10, 20, 30, 50, 100, 200,400 ml, hermetically sealed with rubber stoppers and reinforced with aluminium caps with tamper-evident clips.

1.4 Gentalux is stored in a dry, dark place at temperatures from + 5 ° C to + 25 ° C. Shelf life - two years from the date of manufacture, subject to storage conditions. After opening the bottle, the veterinary medicinal product is stored for 3 days.

**2. PHARMACOLOGICAL PROPERTIES**

2.1 Gentamicin is an antibiotic from the aminoglycoside group. Gentamicin is bactericidal and is active against many strains of Gram-positive and Gram-negative pathogens including species of *Escherichia coli*, *Salmonella spp.*, *Klebsiella spp.*, *Campylobacter spp.*, *Pseudomonas aeruginosa*, *Proteus spp.*, *Treponema hyodysenteriae*, *Corynebacterium*, *Staphylococcus spp.* (included strains resistant to penicillin and methicillin). The veterinary medicinal product is less active against streptococci, does not act on anaerobic bacteria, pathogenic fungi and viruses.

2.2 Gentamicin, actively penetrating the bacterial cell membrane, binds to the 30S subunit of bacterial ribosomes and inhibits the protein synthesis of the pathogen.

2.3 After intramuscular administration, it is rapidly and almost completely absorbed. The maximum concentration in blood plasma occurs after 30-90 minutes and is maintained at a therapeutic level for 6-8 hours. Crosses the placenta. Not metabolized.

2.4 Gentamicin is excreted unchanged in microbiologically active form predominantly via the kidneys (70-95%), partly via faecal excretion.

**3. DOSAGE AND INDICATIONS**

3.1 Gentalux is indicated for cattle and pigs with gastrointestinal, respiratory pathologies, sepsis, peritonitis, pyelonephritis, arthritis and other diseases of animals of bacterial etiology caused by microorganisms sensitive to antibiotics.

3.2 The veterinary medicinal product is administered intramuscularly twice a day with an interval of 10-12 hours for at least 5 days in the following doses, in accordance with the table.

Table - Veterinary medicinal product dosage

<b>Target species</b>	<b>Recommended dosage</b>
Cattle	0.75-2.0 ml per 10 kg of animal weight (3-8 mg of Active substance per 1 kg of animal weight)
Pigs	1.0-1.5 ml per 10 kg of animal weight (4-6 mg of Active substance per 1 kg of animal weight)

3.3 Adverse reactions: ototoxic and nephrotoxic effect, individual hypersensitivity to the veterinary medicinal product components. If symptoms of an allergic reaction appear in animals, the veterinary medicinal product is discontinued and, if necessary, symptomatic therapy is prescribed.

3.4 Contraindications. The use of the veterinary medicinal product is contraindicated in case of hypersensitivity to gentamicin. Use with caution in case of toxic infections.

3.5 Simultaneous use of the veterinary medicinal product with penicillins, cephalosporins, aminoglycoside antibiotics, colistin, polymyxin and sulphanilamides is not allowed.

3.6 Slaughtering of animals for human consumption is allowed no earlier than 21 days after the last administration of the veterinary medicinal product.

Meat of animals and poultry, forced to be killed before the expiration of the specified period, can be used as feed for carnivores.

3.7 Milk must not be used for human consumption within 3 days after the last administration of the veterinary medicinal product.

Before the expiration of the specified period, it is feed to animals after heat treatment.

#### **4. PREVENTIVE MEASURES**

4.1 Generally accepted personal hygiene measures and safety rules should be observed when working with this veterinary medicinal product.

#### **5 CLAIMING PROCEDURE**

5.1 In case of complications after the use of the veterinary medicinal product, its use is discontinued and the consumer should apply to the State Veterinary Institution on the territory of its location. Veterinary specialists of this institution study compliance with all the rules for the use of the veterinary medicinal product in accordance with the instructions. After the confirmation of a veterinary medicinal product adverse effect to the animal, the veterinary specialists take samples in the required amount for laboratory tests, at least three unopened vials of the veterinary medicinal product from the batches that caused the complication, a sampling report is drawn up and sent to the State Institution "Belarusian State Veterinary Center" (220005, Minsk, Krasnaya Str. 19-a, tel. 290-42-75) for confirmation of compliance with regulatory documents.

#### **6 FULL NAME OF MANUFACTURER**

6.1 Stovek, LLC, Republic of Belarus, 222660, Minsk Region, Stolbtsy, Zadvoryenskaya St., 2 for TrionisVet, 141092, Russia, Moscow region, Korolev, md. Yubileynyj, st. Lesnaya, 14, office 5.

The Summary of Veterinary Product Characteristics was developed by the employees of TrionisVet LLC, (A.Yu. Finogenov, T.A. Soboleva, E.G. Finogenova).

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